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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,668	10/14/2003	Steve Mitchell	KLYCD-05008US1	3396

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EXAMINER

SNOW, BRUCE EDWARD

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 01/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/684,668

Applicant(s)

MITCHELL, STEVE

Examiner

Bruce E Snow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-40 is/are pending in the application.
- 4a) Of the above claim(s) 24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-23 and 26-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/10/04; 12/02/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: additional lds 9/29/04.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 11/19/04 have been fully considered.

Regarding the rejections under 35 U.S.C. 112, second paragraph, applicant's arguments are not persuasive. The Examiner notes figure 1E showing the socket 150 is perpendicular to the keel 114. The drawings do not show the socket and keel being parallel; claims 16 and 17 directly conflict each other. The Examiner believes that the upper plate is being described as the first piece in one claim and the very next, the first piece is the lower plate. Applicant's argument that socket 150 can be alternatively extend between the anterior and posterior sides should be supported in the specification and cited to the Examiner. Similar for claims 22-23. The Examiner further notes that all claimed subject matter must be shown in the figures.

Regarding the rejection of claims 1, 4-12, 14, 21-23, 35-36 under 35 U.S.C. 102(e), as being anticipated by Ferree (2004/0106998), applicant states, "*in contrast to independent Claims 1, 35 and 36 of the present invention, Ferree does not teach first and second sockets, whereby the crossbar member is at least partially received within the first and second sockets.*" This is not correct. Clearly the crossbar is received within at least one socket in the upper plate and at least one socket in the lower plate to form a pivot point. A socket is generally defined as:

sock·et (sòk'ĭt) *noun*

1. An opening or a cavity into which an inserted part is designed to fit: *a light-bulb socket.*

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2. *Anatomy.* a. The concave part of a joint that receives the end of a bone. b. A hollow or concavity into which a part, such as the eye, fits.¹

Regarding the rejection of claims 1-23 and 26-36 under 35 U.S.C. 102(e) as being anticipated by Wagner et al (6,706,070), specifically claim 26, applicant states that the “I” strut does not have a first beam mounted at least partially above and across the second beam. The Examiner strongly disagrees. An “I” beam comprises three beams in which the top horizontal beam meets this language when contrasted with a center vertical beam.

Regarding applicant's main argument that the device of Wagner is a vertebrae fusing device, the Examiner agrees. Applicant further argues the upper and lower engaging plates are not supposed to move, the Examiner strongly disagrees. The abstract of Wagner reads:

“Alignment devices for promoting spinal fusion between neighboring vertebrae are disclosed. The alignment device may be use to alter the vertical height between the engaging plates to customize the apparatus to fit a given patient. In one embodiment, the alignment device includes two turnbuckles and two pairs of cam blocks for adjusting the height between a pair of engaging plates. The alignment device may be adapted to vary the height between the engaging plates such that the height of the apparatus proximate a first side edge is substantially different from a height of the apparatus proximate a second side edge.”

It is the Examiner's position that when the height of different side edges can be adjusted differently, this fulfills the claim language “wherein at least the first piece is capable of pivoting about the crossbar member. None of applicant's claims define over Wagner.

¹ *The American Heritage® Dictionary of the English Language, Third Edition* copyright © 1992 by Houghton Mifflin Company. Electronic version licensed from INSO Corporation; further reproduction and distribution restricted in accordance with the Copyright Law of the United States. All rights reserved.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Applicant uses many different terms to describe the upper and lower plates including first piece, second piece, first member, second member. All claim language must be supported in the specification.

Claim Rejections - 35 USC § 112

Claims 16-20 and 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 16-20, the configurations described appear to conflict each other. Please direct to the specification and drawings for support. Diagrams would be helpful.

Regarding claims 22-23 directly conflict each other. Please direct to the specification and drawings for support. Diagrams would be helpful.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Discussion: the definition of the claim terminology "crossbar" is defined as:

cross·bar (krōs'bār', krōs'-) *noun*

A horizontal bar, line, or stripe.²

Claims 1, 4-6, 9-12, 14, 21-23, 35-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Ferree (2004/0106998).

Note that the provisional application No. 60/416,181 was filed on October 4, 2002 and supports figures 1-6 only. Ferree teaches an implant comprising a first piece 104 having a first socket a second piece 104' having a second socket and a

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crossbar member 102 that is at least partially received in the first socket and the second socket.

The crossbar member includes first and second bars configured perpendicular forming a "T" or "+" shape.

Regarding claim 5, the socket or interior surfaces comprise many different slopes.

Claims 1-6, 9-23 and 26-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Wagner et al (6,706,070).

Applicant must consider all configurations taught by Wager, a couple configurations are specifically discussed. Referring to figures 8-9, Wagner et al teaches an implant comprising a first piece 12 having a first socket 60, a second piece 14 having a second socket 60 and a crossbar member 30 that is at least partially received in the first socket and the second socket.

Regarding claim 2 having first and second bars that are perpendicular, see figure 6B showing element 30 having generally "I" shape having upper and lower bars separated by a middle bar. **Also see figures 42-49 wherein the spacer (crossbar) includes at least elements 740, 760 and the cam block. All other elements are self-evident. See the embodiments shown in figure 38 wherein the bars abut.**

Claims 3 and 26, inherently the "I" shape has a bar above the middle bar. Also, referring to figure 9, another interpretation the first bar 30 is mounted higher or above second bar 32.

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Regarding claim 12, see at least figure 42.

Regarding at least claims 15-20 claiming a keel, see at least elements 516, 616, 716, 816, 916, 1016.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferree (2004/0106998) in view of Marnay (WO 01/01893).

Ferree teaches the implant as described above, however, fails to teach a keel. Marnay teaches the keel configuration as claimed. It would have been obvious to one having ordinary skill in the to have used the keel/s of Marnay on the implant of Ferree to better anchor it to the vertebrae.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

bes

A handwritten signature in black ink, appearing to read 'BSN', with a long horizontal stroke extending to the right.

BRUCE SNOW
PRIMARY EXAMINER